UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,773	11/04/2003	Hongming Chen	TPI5020USNP	5482

27777 7590 07/22/2009

PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
HYUN, PAUL SANG HWA	

ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
07/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/700,773	CHEN ET AL.	
	Examiner	Art Unit	
	PAUL S. HYUN	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-24* is/are pending in the application.

4a) Of the above claim(s) *1-5 and 7-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed by Applicant on March 20, 2009 has been acknowledged. Claims 1-5 and 7-24 are currently pending wherein claims 1-5 and 7-18 remain withdrawn pursuant to a previous restriction requirement. Applicant amended claim 19 and added new claims 23 and 24.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims **19-24** are rejected under 35 U.S.C. 103(a) as being unpatentable over McMahon et al. (US 6,004,967) in view of Mulye et al. (US 6,416,786 B1), Lee et al. (US 2003/0230488 A1), Bissett (US 2004/0076546 A1) and Cheng et al. (US 2003/0028330 A1) as evidenced by Fisher Scientific MSDS.

McMahon et al. disclose a method for determining the solubility of the pharmaceutical compound "A1" (see Table 1 in col. 19 for identity of A1) in various excipients wherein the pharmaceutical preparation can comprise solids or non-aqueous liquid (see lines 6-48, col. 17 and Table 4 in col. 20). Specifically, Table 4 shows the solubility of compound A1 having concentration of 10 mg/mL in two different concentrations of polysorbate-80 excipient. Polysorbate-80 has viscosity 400 cP (see Fisher Scientific MSDS which indicates that the viscosity of polysorbate-80 is 400 mPas at room temperature, which corresponds to 400 cP). The method disclosed by McMahon et al. differs from the claimed invention in that McMahon et al. do not disclose the steps of conducting the experiment in an array format using less than 250

microliters of the excipient dispensed by a positive displacement pump. McMahon et al. also do not disclose mixing excipients to explore the synergistic effects of mixing excipients. McMahon et al. also do not disclose conducting solubility testing in liquid that simulates gastric fluids. Lastly, McMahon et al. do not disclose ranking the drugs based on solubility.

With respect to the pump and the array, Lee et al. disclose an apparatus for conducting solubility tests (see [0005]). The apparatus comprises a microplate (see [0047]), and a positive displacement pump (see [0039]) capable of dispensing 2-10 microliters of highly viscous liquid into the wells of the microplate (see [0067]-[0068]). In light of the disclosure of Lee et al., it would have been obvious to one of ordinary skill in the art to conduct the solubility test disclosed by McMahon et al. using the apparatus disclosed by Lee et al. The apparatus disclosed by Lee et al. would optimize the organization as well as the efficiency of the solubility test.

With respect to mixing excipients, Mulye et al. disclose that it is well known in the art to use a mixture of different excipients for pharmaceutical drugs because certain excipient mixtures exhibit synergistic effects, such as unexpected release properties (see lines 15-21, col. 2). In light of the disclosure of Mulye et al. it would have been obvious to mix various combinations of excipients in the solubility test disclosed by McMahon et al. to explore the synergistic effects of certain excipient combinations.

With respect to conducting solubility testing in liquid that simulates gastric fluids, Bissett discloses a method of determining the utility of pharmaceutical drugs by conducting solubility tests of the drugs in various liquids, including excipients (see

[0110]) and liquids that mimic gastric juices (see Abstract). In light of the disclosure of Bissett, it would have been obvious to one of ordinary skill in the art to further subject the pharmaceutical drug A1 disclosed by McMahon et al. to solubility tests in liquids that simulate gastric fluids. It is well known in the art that many pharmaceutical drugs are ingested orally and processed in the stomach. Thus, it is logical to test the solubility of drugs in liquids that mimic gastric fluids.

With respect to ranking the samples, Cheng et al. disclose that it is well known in the art to rank the utility of pharmaceutical compounds based on solubility tests (see [0072] and Table 5). That said, it would have been obvious to one of ordinary skill in the art to rank the pharmaceutical compounds as well as the excipients disclosed by McMahon et al. based on solubility to rank them in order of utility.

With regards to claim 20, none of the references explicitly disclose that degraded or decomposed samples are thrown out from the experiment. Nonetheless, it would have been obvious to one of ordinary skill in the art to selectively exclude decomposed or degraded samples to prevent skewed data caused by defective samples.

With respect to claim 21, it would have been obvious to one of ordinary skill in the art to expand the range of parameters (e.g. concentration of excipient, type of excipient) in the modified method disclosed by McMahon et al. such that more than 94 samples are prepared so that a more thorough data can be obtained.

With regards to claims 23 and 24, given that Cheng et al. disclose that the ranking system is based on potential utility, and that solubility is one indication of utility, it would have been obvious to rank the excipients in the order of 1) excipient samples

that do not exhibit precipitation, 2) excipient samples that exhibit precipitation wherein the excipient samples that exhibit precipitation are ranked based on the size or the extent of the precipitation, and then 3) excipient samples that compromise sample integrity, thus rendering the excipient useless.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but they are moot in view of the new grounds of rejection. The amendment necessitated new grounds of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL S. HYUN whose telephone number is (571)272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Paul S Hyun/
Examiner, Art Unit 1797

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797